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| 10/066,551 | 01/31/2002 | Michael A. Apicella | 875.045US1 | 2735 |

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SCHWEGMAN, LUNDBERG, WOESSNER & KLUTH, P.A.
P.O. BOX 2938
MINNEAPOLIS, MN 55402

| EXAMINER | |
|---|---|
| BASKAR, PADMAVATHI | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1645 | |

DATE MAILED: 05/04/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/066,551 | APICELLA ET AL. | |
| | Examiner | Art Unit | |
| | Padmavathi v Baskar | 1645 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *02 February 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1,7,15,21,23-25 and 59* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,7,15,21,23-25 and 59* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *2/2/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

## DETAILED ACTION

1. The amendment filed on 2/2/04 is acknowledged.

### *Drawings*

2. The newly submitted drawings are placed in the application.

### *Status of Claims*

3. Claims 1-58 are pending in the application.

The amendment filed on 2/2/04 has been entered into the record. Accordingly,

New Claim 59 has been added

Claims 2-6, 8-14, 16-20, 22, and 26-58 are canceled.

Claims 1, 7 and 15 have been amended.

Claims 1, 7, 15, 21, 23, 24, 25 and 59 are now pending in the application and currently under examination.

### *Information Disclosure Statement*

4. The information disclosure statement filed on 2/2/04 is acknowledged and a signed coy of the same is attached to this office action.

### *Specification Informalities withdrawn*

5. In view of amendment to the specification, the specification informalities have been withdrawn.

### *Rejection moot*

6. In view of cancellation of claim 5, the rejection under 35 U.S.C. 112 second paragraph is moot.

### *Rejection withdrawn*

7. In view of amendment to the claims 1 and 7, the rejection under 35 U.S.C. 112, second paragraph is withdrawn.

***Claim Rejections - 35 USC 102 withdrawn***

8. In view of applicant's arguments and the Declaration under Rule 1.132 which indicates that the protein p55kD is a secreted protein and not an outer membrane protein, the rejection of claims 1,7, 15, 21 and 23-25 under 35 U.S.C. 102(b) as being anticipated by Paz et al 1995 (Microbiology 141; 913-920) is withdrawn.

9. In view of applicant's arguments, the rejection of claims 1, 7, 15, 21 under 35 U.S.C. 102(b) as being anticipated by Cann et al 1989 (J.Med.Microbiology 30; 23-30) is withdrawn.

***Claim rejection 101 Maintained***

10. The rejection of claim 1 under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter is maintained as set forth in the previous office action.

Claim 1 is rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The product, polypeptide as claimed, has the same characteristics as that found in nature. To overcome this rejection the Examiner suggests the amendment of the claims to include purity limitations, which would distinguish the characteristics of applicant's product from the product, as it exists in nature. It is further suggested that such limitation include the terminology " purified and isolated" (i.e. if such purity is supported in the specification) and/or a description of what applicant's protein is "free of" relative to the natural source. ( see Farbenfabriken of Elberfeld Co. v. Kuehmsted, 171 Fed. 887, 890 (N.D. Ill. 1909) (text of claim at 889); Parke-Davis & Co. v. H.D. Mulford Co., 189 Fed. 95, 103, 106, 965 (S.D.N.Y. 1911) (claim 1); and In re Bergstrom, 427 F.2d 1394, 1398, 1401-1402 (CCPA 1970).

Applicants' arguments 2/2/04 have been fully considered but they are not deemed to be persuasive.

Applicant states that the amendment to the claim 1 reciting that the protein has been "isolated" from N.gonorrhoeae would obviate the rejection. However, the limitation " an isolated" is not set forth in the claim. Therefore, this rejection is maintained.

***Claim Rejection - 35 USC 112, first paragraph Maintained***

11. The rejection of claims 15, 19, 21 and newly added claim 59 (vaccine composition) under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention is maintained as set forth in the previous office action.

Instant claims are evaluated for enablement using the Wands analysis. Many of the factors regarding undue experimentation have been summarized in In re Wands, 858 F.2d 731,8 USPQ2d 1400 (Fed.Circ.1988) as follows:

(1) the nature of the invention, (2) the state of the prior art, (3) the predictability or lack thereof in the art, (4) the amount of direction or guidance present, (5) the presence or absence of working examples, (6) the quantity of experimentation necessary, (7) the relative skill of those in the art, and (8) the breadth of the claims.

Enablement of a "vaccine composition" is considered to rest on a teaching of in vivo administration for purposes consistent with the intended use disclosed in the specification. The disclosed intended use for the claimed vaccine is for the treatment of sexually transmitted gonorrhea disease caused by *Neisseria gonorrhea* infections. Thus, the nature of the invention is a therapeutic vaccine composition used in treatment or prevention. In addition, the instant specification does not teach how to use the vaccine comprising an immunogenic amount of polypeptide SEQ.ID.NO: 4, without undue experimentation, for the prevention, treatment, or cure of a disease in the female patients to which the substance is administered.

The specification discloses the claimed composition can be used as a vaccine. There is insufficient guidance, which would enable one, skilled in the art to use the claimed compositions for their intended purpose, viz., for the generation of a protective immune response against gonorrhea disease caused by Neisseria gonorrhea. At the time the invention was made, vaccines comprising the claimed polypeptide were not routinely used for the treatment of gonorrhea disease caused by Neisseria gonorrhea. The specification lacks guidance by way of general methods or working examples which teach an "effective amount" of the vaccine which would be used for this purpose. Lack of working examples is given added weight in cases involving an unpredictable and undeveloped art, such as immunotherapy gonorrhea disease caused by Neisseria gonorrhea. It is unpredictable whether the claimed composition, which is disclosed as being only immunogenic, would have the added property of generating the protective immune response sufficient to inhibit gonorrhea disease caused by Neisseria gonorrhea because the prior art discloses that the human pathogen *N.gonorrhoeae* is endowed with a wide range of mechanisms that facilitate immune avoidance including antigenic shift in the expression of surface antigens. Because of this antigenic shift the development an effective vaccine has resulted in frustrated attempts (see introduction of Paz et al 1995, Microbiology 141, 913-920). Therefore, it is important to study how this bacterium invades the epithelial

cells, the expression of intercellular adhesion molecules on epithelial cells and the surface antigens of bacteria during the process of invasion first. Applicant's specification (page 2) states that mechanisms by which the gonococcus infects and invades the female genital tract are only at the beginning stage. The specification has not disclosed a link or nexus between the generation of protective immunity and the claimed polypeptide. Further, it is not routine in the art of immunotherapy to use the claimed compositions for this purpose. Accordingly, there is no objective basis upon which the skilled artisan would reasonably be able to determine or predict an amount of the claimed composition/vaccine effective for its intended use. Therefore, undue experimentation would be required to make and use the invention.

Applicants' arguments filed on 2/2/04 have been fully considered but they are not deemed to be persuasive.

Applicant provides the Declaration under Rule 1.132 as evidence to support that the claimed invention is enabled.

The examiner has carefully gone through the Declaration by professor Michael Apicella and understands that the antibody to PLD (phospholipase D/p55 kD), 1307 has the ability to block the infection of cervical cells (endocervical or ectocervical cells) by blocking the access of *N. gonorrhoeae* to the CR3receptor on the surface of the cell (specification at page 48, lines 26 to page 49, line 2). However, the declaration provided by professor Michael Apicella and applicant's arguments have not addressed the issue whether the claimed isolated and purified 55kD protein from *N gonorrhoeae* comprising the amino acid sequence as set forth in SEQ.ID.NO: 4 would block the invasion of *N gonorrhoeae in vivo.*

The examiner understands that the current invention is directed to the development of an effective vaccine for *N gonorrhoeae*. However, enablement of a "vaccine composition" is considered to rest on a teaching of in vivo administration for purposes consistent with the intended use disclosed in the specification. The disclosed intended use for the claimed vaccine is for the prophylactic treatment of infections caused by *N. gonorrhoeae*. Although the specification discloses the claimed composition, and general methods for formulating

compositions in pharmaceutically acceptable carriers, there is insufficient guidance which would enable one skilled in the art to use the claimed compositions for their intended purpose, viz., for the generation of a protective immune response against N. gonorrhoeae. The specification lacks guidance by way of general methods or working examples which teach an "effective amount" of the claimed protein which would be used for this purpose. Lack of working examples is given added weight in cases involving an unpredictable and undeveloped art such as immunotherapy as applicants recognized the problem.

Further, M.P.E.P. §2164.01(c), paragraph 3, recites: When a composition claim is limited by a particular use, enablement of that claim should be evaluated based on that limitation. See *in re Vaeck*, 947 F.2d 488, 495, 20 USPQ2d 1438, 1444 (Fed. Cir. 1991).

Vaccine composition is a " therapeutic agent"; any substance, other than food, used in the prevention or treatment, or cure of disease". While the definition of "vaccine" is broad, it is not so broad to cover **any** use of a substance on or in the body of a subject, only those uses intended to prevent, diagnose, alleviate, treat, or cure a disease within the animal to which the substance was administered. In the instant application, the animal to which the claimed composition is administered is merely being used as a bioreactor to make the antibodies that are used *in vitro*. In addition, the instant specification does not teach how to use the composition, without undue experimentation, for the prevention, treatment, or cure of a disease in the animal to which the substance is administered. Accordingly, there is no objective basis upon which the skilled artisan would reasonably be able to determine or predict an amount of the claimed vaccine composition is effective for its intended use. Therefore, undue experimentation would be required to make and use the invention. Hence the rejection is maintained.

***Claim Rejections - 35 USC 102 Maintained***

The rejection of

12. Claims 1, 15, 21 and newly added claim 59 under 35 U.S.C. 102(b) as being anticipated by Fraser et al 1999, Accession Number AAY 75751 is maintained as set forth in the previous office action.

Fraser et al disclose a novel polypeptide from *N.gonorrhoeae*. (See the attached sequence alignment and abstract) comprising an amino acid sequence, which is 98.2% similar to the claimed SEQ.ID.NO: 4. The polypeptide could be used as vaccine, immunogenic composition or to raise antibodies (see abstract) The antigen to which an immune response has to be elicited is in general in hydrophilic phase, buffer or saline and is routinely used in the art. Characteristic such as p55 is considered as the inherent property of the disclosed polypeptide that is encoded by nucleic acid. In the absence of evidence to the contrary the disclosed prior art anticipated the claimed invention.

It is acknowledged that weight is given to every term in claims 15, 19 and 21 This is why the instant claims drawn to vaccine is scrutinized differently from a composition claim under 112, first paragraph. However, under prior art rejections, the term vaccine must be weighed with the structural limitations of the claim. If the immunogenic composition i.e., vaccine merely comprises a known composition, the term carries little weight absent evidence of structural difference. However, under prior art rejections, the term vaccine is considered as a composition comprising an isolated polypeptide. See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

Applicants' arguments filed on 2/2/04 have been fully considered but they are not deemed to be persuasive.

Applicant states that Fraser et al., Accession Number AAY 75751 sequenced the *Neisseria meningitidis and N gonorrhoeae* genomes and then looked for open reading frames (ORFs) and do not teach or suggest all of the features of the pending claims. They only teach putative ORFS, which might or might not encode a functional protein. Therefore, the examiner is requested to withdraw the rejection of claims.

It is the position of the examiner that the prior art discloses the ORF as well as the protein. Applicant is arguing about the limitation "functional protein" which is not set forth in the claims. Further, the transitional limitation "comprises" similar to the limitations, such as, "has", "includes," "contains," or "characterized by," represents open-ended claim language and therefore does not exclude additional, unrecited elements. See M.P.E.P 2111.03 [R-1]. See

*Molecular Research Corp. v. CBS, Inc., 793 F2d 1261, 229 USPQ 805 (Fed. Cir. 1986); In re Baxter, 656 F.2d 679, 686, 210 USPQ 795, 803 (CCPA 1981); Ex parte Davis, 80 USPQ 448, 450 (Bd. App.1948)* "comprising" leaves "the claim open for the inclusion of unspecified ingredients even in major amounts". On the other hand, the limitation "consisting of represents closed claim language and excludes any element, step, or ingredient not specified in the claim. In *re Gray, 53 F. 2d 520, Il USPQ 255 (CCPA 1931); Ex parte Davis, 80 USPQ 448, 450 (Bd. App. 1948).* Therefore, this rejection is maintained.

13. The rejection of claims 1, 7, 15 and newly added claim 59 under 35 U.S.C. 102(a) as being anticipated by Parkhill 2000, Accession Number B81859 is maintained as set forth in the previous office action.

Parkhill et al disclose a novel polypeptide from *N.meningitidis.* (see the attached sequence alignment and abstract) comprising an amino acid sequence, which is 100% similar to the claimed SEQ.ID.NO: 4. Characteristic such as p55 is considered as the inherent property of the disclosed polypeptide that is encoded by nucleic acid. Since this polypeptide is 100%identical to the claimed polypeptide the source from which it is isolated is considered as a product by process claim. When the reference teaches a product that appears to be the same as, or an obvious variant of, the product set forth in a product-by-process claim although produced by a different source. See In re Marosi, 710 F.2d 799, 218 USPQ 289 (Fed. Cir. 1983) and In re Thorpe, 777 F.2d 695, 227 USPQ 964 (Fed. Cir. 1985). See also MPEP § 2113. Thus, the prior art anticipated the claimed invention.

It is acknowledged that weight is given to every term in claims 15, 19 and 21 This is why the instant claims drawn to vaccine is scrutinized differently from a composition claim under 112, first paragraph. However, under prior art rejections, the term vaccine must be weighed with the structural limitations of the claim. If the immunogenic composition i.e., vaccine merely comprises a known composition, the term carries little weight absent evidence of structural difference. However, under prior art rejections, the term vaccine is considered as a composition comprising an isolated polypeptide. See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

Applicants' arguments 2/2/04 have been fully considered but they are not deemed to be persuasive.

It is the position of the examiner that the prior art discloses the ORF as well as the protein. Irrespective of the source of protein, the disclosed prior art protein is 100% identical to the claimed protein. Applicant is arguing the limitation "functional protein" which is not set forth in the claims. Further, the transitional limitation "comprises" similar to the limitations, such as, "has", "includes," "contains," or "characterized by," represents open-ended claim language and therefore does not exclude additional, unrecited elements. See M.P.E.P 2111.03 [R-1]. See *Moleculon Research Corp. v. CBS, Inc., 793 F2d 1261, 229 USPQ 805 (Fed. Cir. 1986); In re Baxter, 656 F.2d 679, 686, 210 USPQ 795, 803 (CCPA 1981); Ex parte Davis, 80 USPQ 448, 450 (Bd. App.1948)*"comprising" leaves "the claim open for the inclusion of unspecified ingredients even in major amounts". On the other hand, the limitation "consisting of represents closed claim language and excludes any element, step, or ingredient not specified in the claim. In *re Gray, 53 F. 2d 520, Il USPQ 255 (CCPA 1931); Ex parte Davis, 80 USPQ 448, 450 (Bd. App. 1948).* Therefore, claims 1, 7,15, and 59 read on the prior art protein. Claims 1, 7, 15, and 59 stand rejected because irrespective of the source of protein, there are no structural differences between the disclosed protein and the claimed protein as well as a vaccine composition comprising said protein. Therefore, this rejection is maintained.

***New Claim Rejections based on the amendment***

***Claim rejections 101***

14. 35 U.S.C. 101 reads as Follows

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

15. Claim 7 is rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. To overcome this rejection the Examiner suggests the amendment of the claims to include the terminology " purified and isolated" so that protein is "free of" relative

to the natural source. ( see Farbenfabriken of Elberfeld Co. v. Kuehmsted, 171 Fed. 887, 890 (N.D. Ill. 1909) (text of claim at 889); Parke-Davis & Co. v. H.D. Mulford Co., 189 Fed. 95, 103, 106, 965 (S.D.N.Y. 1911) (claim 1); and In re Bergstrom, 427 F.2d 1394, 1398, 1401-1402 (CCPA 1970).

***Claim Rejections - 35 USC 112, second paragraph***

16. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 1, 7, 15, 21, 23-25 and 59 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim1 is vague and indefinite in the recitation of " 55kD". In consideration of the discrepancies often encountered in the art between protein molecular weights when determined by different methods, whenever a molecular weight is recited to characterize a protein the claim should include not only the method by which it was determined, e.g. whether by sodium dodecyl sulphate polyacrylamide gel electrophoresis, gel filtration or some other method, but also whether the determination was made under denaturing or non-denaturing conditions and whether reducing or non-reducing conditions were used. Does applicant intend to mean an isolated and purified 55 kD protein as determined by --- from *N.gonorrhoeae?*

Claim 7 is rejected as being vague for the recitation of " A p55" protein having an amino acid sequence that corresponds essentially to SEQ.ID.NO: 4". In consideration of the discrepancies

often encountered in the art between protein molecular weights when determined by different methods, whenever a molecular weight is recited to characterize a protein the claim should include not only the method by which it was determined, e.g. whether by sodium dodecyl sulphate polyacrylamide gel electrophoresis, gel filtration or some other method, but also whether the determination was made under denaturing or non-denaturing conditions and whether reducing or non-reducing conditions were used. Does applicant intend to mean the claim to recite " An isolated and purified protein 55 kD as determined by --------comprising the amino acid sequence as set forth in SEQ.ID.NO: 4?

Claim 15 is rejected as being vague for the recitation of "a polypeptide p55". In consideration of the discrepancies often encountered in the art between protein molecular weights when determined by different methods, whenever a molecular weight is recited to characterize a protein the claim should include not only the method by which it was determined, e.g. whether by sodium dodecyl sulphate polyacrylamide gel electrophoresis, gel filtration or some other method, but also whether the determination was made under denaturing or non-denaturing conditions and whether reducing or non-reducing conditions were used. Does applicant intend to mean an isolated and purified 55 kD protein as determined by --- from *N.gonorrhoeae?*

Claims 7 and 59 recite "a protein having an amino acid sequence that corresponds essentially to SEQ.ID: NO: 4" As written it is impossible to understand whether applicant is claiming the amino acid sequence SEQ.ID.NO: 4 or some other sequence which corresponds to SEQ.ID.NO: 4 anywhere in the sequence? Does applicant intend to mean an isolated protein having the amino acid sequence as set forth in SEQ.ID.NO: 4?

***Remarks***

17. Claims 1, 7, 15, 21, 23-25 and 59 are rejected.

***Conclusion***

18. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP ' 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for response to this final action is set to expire THREE MONTHS from the date of this action. In the event a first response is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event will the statutory period for response expire later than SIX MONTHS from the date of this final action.

19. Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile transmission. Papers should be transmitted via the PTO Fax Center, which receives transmissions 24 hours a day and 7 days a week. The transmission of such papers by facsimile must conform to the notice published in the Official Gazette, 1096 OG 30, November 15, 1989. The RightFax number for submission of before-final amendments is (703) 872-9306. The RightFax number for submission of after-final amendments is (703) 872-9307.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Padma Baskar Ph.D., whose telephone number is ((571) 272-0853. A message may be left on the Examiner's voice mail system. The Examiner can normally be reached on Monday to Friday from 6.30 a.m. to 4.00 p.m. except First Friday of each bi-week.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (571) 272-0864. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.

Padma Baskar Ph.D.

4/25/04

LYNETTE R. F. SMITH
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER